

Surgical Technique

PIPELINE™
Access System



C O N S U L T I N G S U R G E O N

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I N T R O D U C T I O N

Lumbar discectomy technique has changed significantly over the years since Mixter and Barr performed the first discectomy. In recent years there has been an effort across all disciplines of surgery to minimize the incision, in order to achieve less damage to healthy tissue, permitting faster recovery, less hospital stay (and therefore reduced cost) and usually less pain for the patient.

Orthopaedics and Neurosurgery have seen similar efforts over the years including spinal surgery. Use of the microscope has become commonplace, permitting magnification, illumination and binocular vision. There have been forays into percutaneous discectomy procedures, and more recently use of 2-dimensional endoscopes both rigid and flexible. However, visualization of delicate neuroanatomy on 2-dimensional video monitors, as well as the small working channels with these devices has limited their acceptance and popularity with many surgeons, as well as the limited types of pathology that can be addressed.

With experience and proper education, surgeons are now pursuing interbody fusions, pedicle fixation, anterior and posterior cervical and thoracic spinal surgery through tubular retraction ports.

This surgical technique describes the new PIPELINE™ Access System which permits 3-dimensional visualization of the spine, either with loupes or microscope, adequate illumination and a large enough working portal to perform lumbar discectomy and laminectomy with safety and reliability.

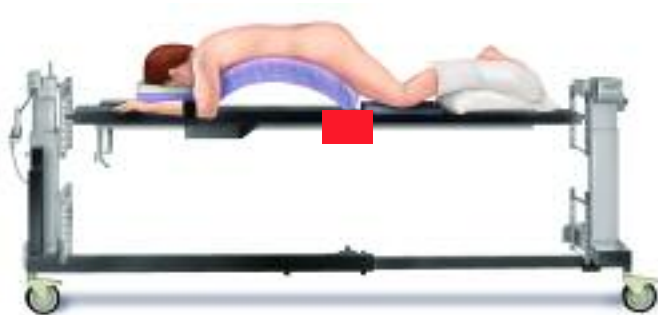
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NOTE: Any operating room table used for image procedures will suffice, though the Jackson table offers an optimal amount of unrestricted fluoroscopic visualization.

Step 1 - Patient Positioning

- Position patient in the prone position. The use of a Wilson Frame on top of a Jackson Table will assist in achieving the proper position and provide an unrestricted view for imaging.



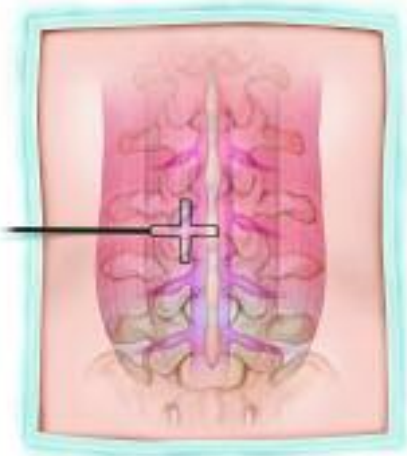
- On the contralateral side to the planned incision, position a Clark Socket (■) on the table rail lateral to the mid or upper thigh to facilitate subsequent placement of the Rigid Arm Assembly.
- Once the surgical preparation and draping are completed, the sterile Rigid Arm Assembly is attached to the table via the Clark Socket with the aid of the circulating nurse.

Step 2 – Anatomical Landmarks

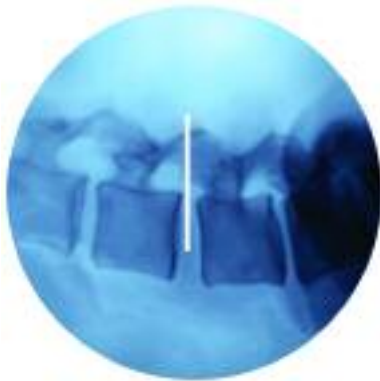
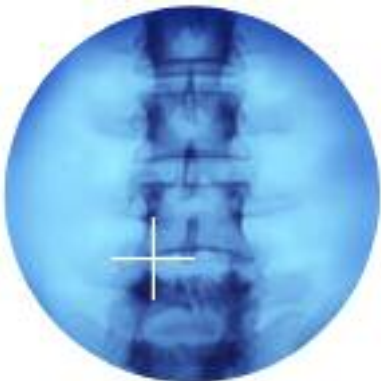


- Dilation of the multifidus and longissimus muscles that run parallel to the spine is the primary objective. Fluoroscopy is used to accurately locate the desired level and close attention is made to keep the targeted surgical site at the center of the fluoroscopic view. A C-arm with AP and Lateral views provide proper imaging.

Step 3 – Targeting



- An Incision Template is used with fluoroscopic guidance to locate the incision's center over the disc space of the proper level to be operated on. A longitudinal incision slightly larger than the desired port diameter is made, usually through skin only, since the dilators will pierce and dilate the fascia.

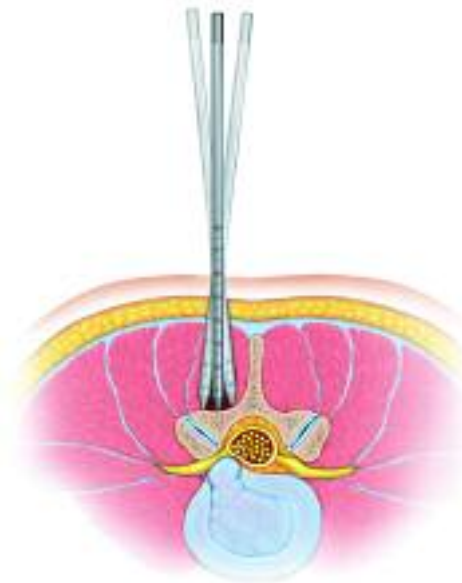


NOTE: Proper targeting is very important to maximize ease of surgery and minimize the need to enlarge the incision. For unilateral lumbar discectomy the center of the target is generally the inferior edge of the cephalad lamina and the medial border of the facet joint of the desired disc level. This incision can be adjusted cephalad or caudal as necessary to retrieve a sequestered fragment, or positioned lateral to the facet joint for an extraforaminal approach to a far lateral or intraforaminal disc herniation.

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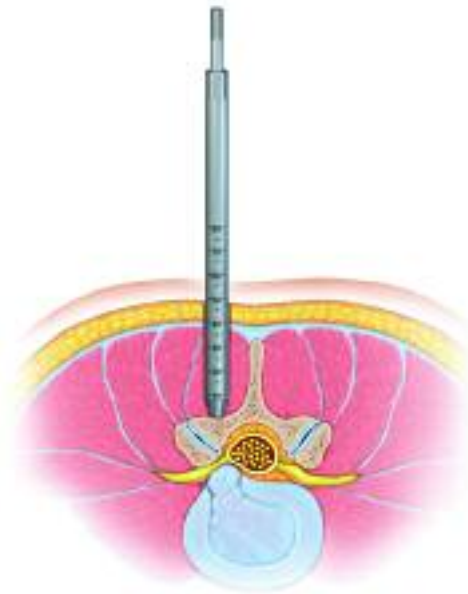
NOTE: If desired, the fascia can be incised prior to the insertion of the First Dilator.

Step 4 - Initial Dilatation



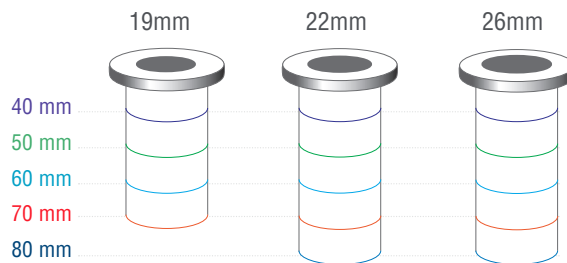
- Once the incision is made, the First Dilator is inserted into the incision, bluntly piercing the fascia to dilate the paravertebral muscle tissue down to the laminar level.
- The first dilator's position is confirmed fluoroscopically. With careful tactile sensation, the paravertebral muscles are swept free from the lamina, base of the spinous process and over the facet joint with a gentle wandering motion to facilitate visualization and ensure the subsequent Dilators and PIPELINE Retraction Ports are fully seated against the laminar bone.

Step 5 – Serial Dilatation & Depth Measurement



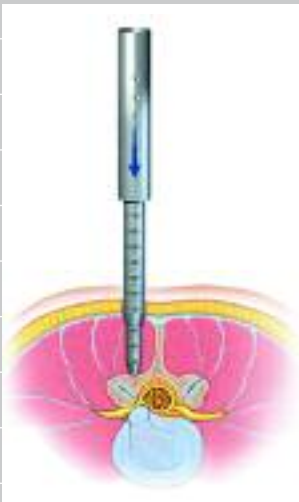
- Sequential dilatation is performed by passing the next largest Dilator over the previously inserted Dilator.
- It is recommended that the depth measurement is taken from the Second or Third Dilators as these will be flush to the bone and produce the most accurate measurement. The depth should be taken at the point where the skin contacts the dilator.

NOTE: The 19mm and 22mm PIPELINE Retraction Ports also come in an angled configuration to provide an alternative interface between the distal tip of the working port and the patient's lamina.



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An Introducer can be utilized to insert the larger Dilators. This may be required to overcome the tension of the fascia and to ensure the Dilators have reached the laminar level.



Step 6 – Serial Dilation Continued



- Continue sequential dilation until the desired diameter is achieved.
- Ports come in 19mm, 22mm and 26mm diameters and the selection of these will determine the number of dilation steps required. Dilation steps for the desired PIPELINE Retraction Port diameters are as follows:
 - 19mm – Dilators 1 through 4
 - 22mm – Dilators 1 through 5
 - 26mm – Dilators 1 through 6

NOTE: Most discectomy surgery can be accomplished with 19 or 22mm ports, though laminectomy and fusion surgery, especially with instrumentation will generally require 22 or 26mm ports.

NOTE: For port lengths greater than 50 mm, the 22 or 26mm diameter ports will improve visualization and ease of surgery.

Step 7 – Port Insertion

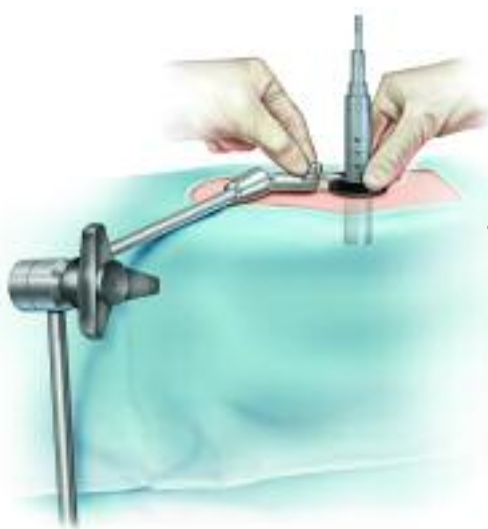


- Once final serial dilation is complete and the proper PIPELINE Retraction Port diameter and length have been determined, the clear PIPELINE Retraction Port can be inserted.
- It is recommended that the surgical assistant holds the Introducer firmly over the Dilators to maintain their position against the lamina while the surgeon inserts the PIPELINE Retraction Port to the laminar level.

NOTE: Irrigating the outer surfaces of the PIPELINE Retraction Port will assist in inserting the device.

CAUTION: It is important to keep the Dilators fully seated on the lamina during the insertion of the PIPELINE Retraction Port to avoid creep of soft tissue underneath the Dilators.

Step 8 – Rigid Arm Attachment



- The Rigid Arm Assembly, which was attached to the surgical table during Step 1, is now connected to the PIPELINE Retraction Port to hold it in place for the remainder of the procedure.
- The Rigid Arm Assembly can be loosened at any point during the procedure to allow the PIPELINE Retraction Port to be angled for an alternate field of view and permit exposure of additional portions of the local spinal region.

CAUTION: When attaching or adjusting the Rigid Arm Assembly, care should be taken to maintain the PIPELINE Retraction Port's position up against the lamina to prevent creep of soft tissue.

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Step 9 - Removal of the Dilators



- Once the PIPELINE Retractor Port has been fully positioned to the laminar level, and the Rigid Arm Assembly has been tightened, the Dilators can be removed.
- Care should be taken to ensure the PIPELINE Retractor Port remains fully seated during this step.

Step 10 – Initial Dissection



- Electrocautery can be used to remove any remaining muscle attached to the bone inside the PIPELINE Retractor Port. This prevents bleeding or oozing from the tissues. Gently palpate the bone with an inactive, extended length bovie tip to ensure that it is against bone and not in the canal. A pituitary rongeur can be used to pluck the tissue fragments out of the exposure. Irrigation can be used routinely to ensure adequate visualization during these maneuvers.
- The lamina, ligamentum flavum and lateral border of the canal can easily be identified. The spinal canal is entered by dissecting the ligamentum flavum off the caudal edge of the lamina.
- An upcutting curette is ideal to elevate the ligamentum flavum from the lamina and sweep it from midline laterally.

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Step 11 – Hemilaminotomy



- Until the thecal sac is identified directly, the ligamentum flavum will act as protection to the dura during hemilaminotomy. Then the ligamentum flavum can be resected with angled Kerrison Ronguers, which permits proper identification of the disc herniation and allows for appropriate thecal sac and nerve root retraction. If necessary, a high-speed burr can be easily and safely used to remove hypertrophic bone and thin the lamina or medial facet. Special bayoneted instruments, such as a Penfield 4, can be used to facilitate visualization of the neuroanatomy and disc.
- A paste made from SURGIFOAM™ Absorbable Gelatin Powder is very helpful to stop the oozing from the cut bony surfaces, filling the cancellous surfaces produced by the hemilaminotomy, as well as small epidural vessels.

Step 12 – Discectomy



- Discectomy ensues.

NOTE: Careful attention to clearing the floor of the spinal canal from epidural vessels with the bipolar electrocautery prior to incision of the PLL or annulus will decrease bleeding and ensure continued proper visualization. Place only one instrument in the PIPELINE Retraction Port at a time.

Top down view of final discectomy.



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NOTE: An anesthetic mixture of 1% Lidocaine and 0.5% Marcaine without epinephrine can be used to reduce post-operative incisional pain. Liberally inject the tissues surrounding the dilated region, using a total of about 20 cc.

Step 13 – Closing



- The PIPELINE Retraction Port can then be removed. A local anesthetic delivered via a spinal needle into the deep muscular tissues, around the facet joint, as well as the fascia and subcutaneous tissues, is performed under direct vision while the PIPELINE Retraction Port is removed. This may assist with post-operative discomfort.
- The fascia is closed with a single suture and the skin is closed with subcuticular sutures which minimizes local scarring. DERMABOND™ Topical Skin Adhesive will reinforce the skin closure. A BAND-AID® Brand Adhesive Bandages is the final dressing.

Ordering Information

PRODUCT CODE	DESCRIPTION
2882-01-001	Introducer
2882-01-004	Incision Template
2882-01-005	1st Dilator, 5mm
2882-01-010	2nd Dilator, 10mm
2882-01-014	3rd Dilator, 14mm
2882-01-018	4th Dilator, 18mm (19mm Port)
2882-01-021	5th Dilator, 21mm (22mm Port)
2882-01-025	6th Dilator, 25mm (26mm Port)
2882-01-030	Case & Tray
2882-01-040	Rigid Arm
2882-19-040	19mm x 40mm Dilation Port
2882-19-050	19mm x 50mm Dilation Port
2882-19-060	19mm x 60mm Dilation Port
2882-19-070	19mm x 70mm Dilation Port
2882-19-140	19mm x 40mm Angled Dilation Port
2882-19-150	19mm x 50mm Angled Dilation Port
2882-19-160	19mm x 60mm Angled Dilation Port
2882-19-170	19mm x 70mm Angled Dilation Port
2882-22-040	22mm x 40mm Dilation Port
2882-22-050	22mm x 50mm Dilation Port
2882-22-060	22mm x 60mm Dilation Port
2882-22-070	22mm x 70mm Dilation Port
2882-22-080	22mm x 80mm Dilation Port
2882-22-140	22mm x 40mm Angled Dilation Port
2882-22-150	22mm x 50mm Angled Dilation Port
2882-22-160	22mm x 60mm Angled Dilation Port
2882-22-170	22mm x 70mm Angled Dilation Port
2882-22-180	22mm x 80mm Angled Dilation Port
2882-26-040	26mm x 40mm Dilation Port
2882-26-050	26mm x 50mm Dilation Port
2882-26-060	26mm x 60mm Dilation Port
2882-26-070	26mm x 70mm Dilation Port
2882-26-080	26mm x 80mm Dilation Port



I N D I C A T I O N S

To provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the retractor, down to the lamina, with its attachment to a flexible arm to provide a self-locking method of access to the spinal site through which a microscope and surgical instruments can be manipulated.

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WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

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